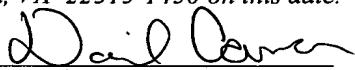


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## APPARATUS FOR EXPRESSING MILK

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## APPARATUS FOR EXPRESSING MILK

1           This is a continuation-in-part of Serial No. 09/715,990, filed November 17,  
2         2000, which is a continuation-in-part of Serial No. 09/591,981, filed June 12, 2000.

### 3           FIELD OF THE INVENTION

4           This invention relates to apparatus for extracting milk, and more  
5         particularly, to breast pumps which are convenient and comfortable to use.

### 6           BACKGROUND OF THE INVENTION

7           Pumps for expressing milk from breasts are well-known. One known breast  
8         pump is disclosed in Whittlestone U.S. Patent No. 4,607,596.

9           The Whittlestone patent discloses a breast pump having two milk collectors  
10        connected to a pump which applies both a vacuum and pulsating pressure to the breasts  
11        to extract milk. The pulsating pressure reciprocates between positive and negative  
12        (vacuum) pressure. The pulsating pressure gently massages and compresses the breasts  
13        to stimulate milk production, and the vacuum secures the milk collectors to the breasts  
14        and helps draw the milk and collect it. The pulsating pressure actually cyclically  
15        increases the vacuum level at the breast(s), which further stimulates milk production.  
16        However, the pressure is not relieved during pulsation in the Whittlestone patent, so

1 pressure can build to a level sufficient to stall a small motor in a well-sealed system. In  
2 addition, the amplitude of the pressure pulses can be reduced by pressure build-up, which  
3 is also undesirable. Thus, there is a need for breast pumps that use pulsation as well as  
4 vacuum to draw milk, and have controlled relief of the pressure during operation.

5               In the Whittlestone device, milk from the two collectors is commonly drawn  
6 into a first collection vessel, and then a second collection vessel. The milk is drawn  
7 through vacuum lines, though, which makes cleaning difficult. Accordingly, there is a  
8 need for breast pumps which are more sanitary and easier to clean than the Whittlestone  
9 device.

10               The Whittlestone patent discloses a breast cup having a housing, a relatively  
11 soft inner ring or donut, and a flexible liner. The liner wraps around the outlet of the cup,  
12 and a bung is inserted into the cup outlet to pass the vacuum and milk. At the inlet side,  
13 the liner is simply folded over the outside of the housing. This design has limitations.  
14 The liner is not accurately aligned and reliably sealed on the inlet side, so moisture and  
15 other contaminants can get inside the liner, which is undesirable. At the outlet, the nipple  
16 can contact the bung and the liner can collapse around the breast, which can be  
17 uncomfortable, and can cause unnecessary trauma, including potential abrasion at the tip  
18 of the nipple. Accordingly, there is a need for breast pumps having cups which better fix  
19 the liner to the housing. There is also a need for breast pump cups which protect at least  
20 the end of the nipple from discomfort due to pulsating pressure.

21               The breast pump disclosed in the Whittlestone patent is a diaphragm pump  
22 operated by an electric motor. Rotation of the motor shaft is translated into back and forth

1 action by a somewhat large and cumbersome linkage which moves the diaphragm. This  
2 adds not only size but weight to the pump, as well. Moreover, the motor must be fairly  
3 large, in part because a high vacuum is needed for cleaning purposes, and to maintain  
4 adequate vacuum and pressure if the system is leaky. These are problems because  
5 convenient storage and portability are desirable to breast pump users. Thus, there is a  
6 need for breast pumps which are lighter and smaller than known devices.

7 Accordingly, one object of this invention is to provide new and improved  
8 apparatus for extracting milk from breasts.

9                   Another object is to provide new and improved breast pumps which are  
10                  more convenient and comfortable to use.

Another object is to provide new and improved breast pumps that use both vacuum and pulsation pressure to collect milk, and control the pulsation pressure to maintain consistent, predetermined increases in the vacuum as the milk is collected.

14 Still a further object is to provide new and improved breast pumps which  
15 are more sanitary, easy to clean and easy to disassemble and re-assemble in the field.

16 Yet another object is to provide new and improved breast pumps which are  
17 relatively light, compact and portable.

18 SUMMARY OF THE INVENTION

19 A device for expressing milk from one or both breasts has at least one milk  
20 collector and a pump. Preferably, the device has first and second collectors (also called  
21 expressers), so that both breasts can be milked simultaneously. Each expresser has a cup

1 assembly which fits on the breast, a pulsation port to which a supply of pressurized  
2 pulsating air is connected, and a vacuum port to which a vacuum supply is connected.  
3 The pulsating air and vacuum are created by the pump. In use, pulsating air causes  
4 massage and gentle compression of the breast and stimulates milk production, while the  
5 vacuum secures a liner in the collector on the breast and expresses the milk from the  
6 breast. Among other things, the pressure pulses increase the vacuum at the breast.

7 Both vacuum and pulsating air pressure are fairly well controlled by  
8 adequately sealing the various parts of the device and providing a pressure release vent  
9 for the pressurized air supply to each expresser. A vacuum adjustment is also provided.

10 The collectors also include a cap and manifold which direct the vacuum and  
11 pressure, a cup assembly which is preferably press fit onto the manifold, a collection  
12 vessel secured to the bottom of the manifold, and, if desired, a one-way check valve or  
13 the like between the manifold and the collection vessel. After passing through the  
14 vacuum adjustment, the vacuum is directed through the cap and manifold, collection  
15 vessel and cup assembly so that the milk is drawn into the collector with little or no milk  
16 entering the vacuum lines to the pump. A filter may be provided for added isolation of  
17 the vacuum pump and vacuum lines, if desired.

18 The cup assembly includes a bell housing, a relatively soft donut shaped  
19 pad, and the flexible liner, preferably made of silicone, nitrile or other suitable material  
20 that meets requirements for medical materials. The liner is secured to the inlet side of the  
21 cup assembly by a locking type of attachment, and extends around the bottom or lower  
22 end of the bell housing, where it is secured by another locking press fit configuration.

1                   The bottom end of the cup assembly fits into a receptacle in the manifold.  
2                   The receptacle has a hollow boss which extends into the cup assembly by a desired  
3                   distance. The hollow portion inside the boss increases the area for extension of the nipple  
4                   during milk expression, avoiding potentially uncomfortable contact at the nipple area.  
5                   The boss also prevents the liner from collapsing around the end of the nipple during use,  
6                   and keeps the throat of the cup assembly open for milk flow.

7                   The collector can be easily disassembled and cleaned in a dishwasher or the  
8                   like, by removing the collection vessel and using or storing the milk, removing the cap  
9                   and then removing the cup assembly. The cup assembly can be cleaned without removing  
10                  the liner, if desired, or the liner can be removed and cleaned separately, or replaced. A  
11                  cleaning cap can be placed over the air pulsation port of the cup assembly when the cup  
12                  assembly is cleaned in its assembled condition, to prevent water from entering the space  
13                  between the liner and the bell housing. A valve could be used in place of the cap for this  
14                  purpose, if desired.

15                  The manifold, cap and valve can also be washed. The cup assembly can be  
16                  easily reassembled after cleaning by reinserting the cup assembly in the manifold, re-  
17                  attaching the cap to the manifold and cup assembly, and securing another collection vessel  
18                  to the bottom of the manifold, with or without the check valve.

19                  The pump includes a movable diaphragm in a chamber. The diaphragm is  
20                  oscillated back and forth by a relatively small linear actuator device such as a stepper  
21                  motor. The motor preferably is a self-contained system that moves its final object axially.  
22                  The motor can have a shaft which does not rotate, but moves back and forth axially. The

1 shaft of the motor is directly or nearly directly linked to the diaphragm, which eliminates  
2 complex and cumbersome linkage components, reducing the size and weight of the pump.

## BRIEF DESCRIPTION OF THE DRAWINGS

4 The above mentioned and other features of this invention and the manner  
5 of obtaining them will become more apparent, and the invention itself will be best  
6 understood with reference to the following description of an embodiment of the invention  
7 taken in conjunction with the accompanying drawings, in which:

8 Fig. 1 is a partially cut-away perspective view of apparatus made in  
9 accordance with the principles of this invention;

10 Fig. 2 is a milk collector used in the apparatus of Fig. 1, shown in cross-  
11 section;

Fig. 3 is a top view of the milk collector of Fig. 2, taken along lines 3-3 in Fig. 2;

14 Fig. 4 is an exploded view of a cup assembly used in the collector of Fig.  
15 2;

Fig. 5 is an exploded view of the collector of Fig. 2;

17 Fig. 6 is a cut-away view of the collector of Fig. 2, showing the liner in a  
18 collapsed condition;

19 Fig. 7 is a graph showing the effect of pressure pulsation on the vacuum at  
20 the liner of the collector of Fig. 2;

Fig. 8 is a cut-away view of an alternate embodiment of the pump used in the apparatus of Fig. 1;

Fig. 9 is a block diagram of a control system for the apparatus of Fig. 1;

Figs. 10 and 11 are diagrams of an alternate embodiment of the diaphragm used in the pump in the apparatus of Fig. 1; and

Fig. 12 is a cutaway view of a connector used in the apparatus of Fig. 1.

## **DETAILED DESCRIPTION**

Referring to Fig. 1, apparatus 10 is provided for expressing milk from one breast, or from two breasts simultaneously. The apparatus 10 includes a first collector or expresser 12 and a second expresser 14. It is likely that both expressers would generally be used, but only one expresser could be used, if desired, preferably by disconnecting the vacuum line from the unused expresser and covering the unused vacuum port of the pump with a cap (not shown).

A pump 16 is connected to both expressers 12, 14 through vacuum lines 18, 20, and air pressure lines 22, 24. The vacuum and pulsation lines can be configured in any suitable way. In Fig. 1, vacuum hoses 18a, 20a and pressure hoses 22a, 24a are connected to the pump 16 and a connector 17. Vacuum hoses 18b, 20b and pressure hoses 22b, 24b are connected to the other end of the connector 17 and the expressers 12, 14 with adapters 23 (Figs. 2, 3), if needed. The connector 17 has openings for the lines 18, 20, 22 and 24, and a throat 19 which connects the vacuum lines 18, 20 to each other, creating a common vacuum at the expressers 12, 14, as seen in Fig. 12. A threaded needle

1 valve 21 in the throat 19 permits easy adjustment of the vacuum by venting atmospheric  
2 air into the system as desired. The connector 17 can be secured to a housing, if desired,  
3 to provide easy vacuum and pressure transmission through the housing.

4 The pump 16 creates a vacuum which engages the breasts, and contributes  
5 to drawing the milk from the breasts. The pump also creates reciprocating compression  
6 and release pressure pulsation around the areola and some or all of the nipple, as will be  
7 seen. The pump 16 can be powered by line voltage, a battery, manually or the like.

8 The expressers 12, 14 are shown in greater detail in Figs. 2, 3 and 5. Each  
9 expresser includes a manifold 26, a cup assembly 28 which fits over a breast, a cap 30,  
10 a filter 31 (Fig. 5), a sealing device 33a such as a wipe washer, o-ring or the like, and a  
11 collection vessel 34 . Gaskets 33b and 33c are also included, to better seal the vacuum  
12 system. A valve 36 can be included, though it is not necessary. The collection vessel can  
13 be a bottle made of plastic-like material or the like or a bag, and can be oriented at an  
14 obtuse angle with respect to the cup assembly, as shown.

15 The manifold 26 includes an opening 38 which is preferably threaded, so  
16 that a collection vessel such as a plastic milk bottle can be threadedly secured to the  
17 manifold 26, with the valve 36. The valve 36 is preferably a one-way check valve such  
18 as a duck bill valve or the like. When using the valve 36, the gasket 33c is not needed  
19 because the valve 36 seals the opening 38. A vent 37 in the manifold 26 is helpful  
20 because it keeps the collection vessel 34 at atmospheric pressure when the valve 36 is  
21 used. However, it is also possible to eliminate the valve 36, in which case there is also  
22 no need for the vent 37.

1           A vacuum is applied to the expresser through a port 42 in the cap 30, and  
2       is drawn through a vacuum path in the manifold 26 through an outlet opening 44 in the  
3       top of the manifold. The vacuum is drawn through an internal orifice 46 to the opening  
4       38 in the midsection of the vacuum path, which is beneath the port 42 and the cup  
5       assembly 28. The vacuum tends to close the valve 36, which in conjunction with the vent  
6       37, prevents a substantial buildup of vacuum in the collection vessel 34.

7           The vacuum is drawn from the opening 38 to a manifold vacuum inlet 40  
8       through a channel 50. The vacuum inlet 40 forms a cup assembly opening that is in  
9       communication with a milk outlet port 48 in the cup assembly 28. When milk is drawn  
10      from the breast, the milk passes through the channel 50 under the force created by the  
11      vacuum, but most of the milk drops into the valve 36 through the force of gravity, and  
12      does not enter the orifice 46. Cleaning is easier because milk is not drawn into the  
13      vacuum path beyond the collection vessel 34. When sufficient milk collects in the valve  
14      36, the weight of the milk forces the valve open, which releases the milk into the  
15      collection vessel 34. Because the milk falls down, the vacuum lines are not  
16      contaminated. In this manner, the milk is collected without contaminating the vacuum  
17      lines 18, 20 (Fig. 1).

18           The cup assembly 28 has a milk inlet port 52 in addition to the outlet port  
19      48. The components of the cup assembly 28 include a bell housing 54, a donut shaped  
20      pad 56, and a flexible liner 58, shown disassembled in Fig. 4. The cup assembly 28 also  
21      has an air pressure pulsation port 60 which forms part of a pressure path and allows  
22      pressurized air to enter a space 62 between the case bell housing 54 and the liner 58.

1                   The cup assembly 28 is assembled by placing the donut shaped pad 56 in  
2                   the housing 54 as shown, and does not need further securement. The pad 56 is preferably  
3                   made of a suitable foam material which is sized to fit snugly in the housing 54. However,  
4                   the pad 56 can be easily removed by placing a finger through the opening in the ring and  
5                   pulling the ring out.

6                   The liner 58 is installed in the cup assembly 28 by securing an end 63 to the  
7                   liner 58 in a groove 64 formed in the housing 54 (Figs. 2, 3 and 4). The end 63 and  
8                   groove 64 are shaped to provide locking press fit type of securement. The liner could also  
9                   be affixed to the housing 54 by heat or chemical bonding.

10                  The liner 58 extends from the groove 64 over and around the pad 56 and  
11                  inside of the housing 54 to a bottom end 66 of the housing 54. An end 68 of the liner 58  
12                  is inserted into a groove 70 near the end 68 for securement in a press fit fashion. The  
13                  liner 58 can be any suitable shape, including the shape shown in Fig. 2, which includes  
14                  a relatively narrow section 72 near the inlet opening 52, and a wider section 74 between  
15                  the section 72 and the outlet end 48 of the cup assembly 28. This shape places more  
16                  pressure around the areola region of the breast, while placing less pressure on the nipple  
17                  itself. By sealing the liner to the case at both ends, the assembly can be washed without  
18                  taking the liner off, if a cleaning cap 75 is placed over the pressure inlet 45 (Fig. 4).

19                  The cup assembly 28 can be press fit into a circular groove 76 in the  
20                  manifold 26, seen in Fig. 5. The groove 76 is formed by an outside wall 78 and an inside  
21                  boss 80. The boss 80 can extend outwardly as far as desired, and can be any suitable  
22                  shape, such as circular, triangular, square, rectangular, elliptical, hexagonal, etc. Since

1       the boss 80 is hollow and prevents the liner 43 from collapsing under outside air  
2       pressure, the boss 80 protects any part of the nipple which is inside the boss from a  
3       pinching action caused by pressure when the liner is collapsed, as seen in Fig. 6.  
4       Abrasion is avoided because there is more room for breast extension during milk  
5       expression. The boss 80 also keeps the throat of the cup assembly open, so that the flow  
6       of milk is not inhibited.

7                  The cap 30 (Figs. 2, 3 and 5) includes an air pressure/pulsation channel 82  
8       which extends from a pressure inlet 84 to the port 60, as well as the port 42 for the  
9       vacuum path. The cap 30 can be press fit over the manifold opening 44 and the cup  
10      assembly air pressure/pulsation port 60, and can be easily removed. When installed, the  
11      cap 30 further secures the cup assembly in the manifold, but both the cap and the  
12      manifold can be removed without tools for cleaning purposes.

13                  The filter 31, if used, further prevents liquids, fats and solid components in  
14       the milk from entering the vacuum lines and the pump. The filter 31 is preferably  
15       permeable to air flow when dry and also when wet, which can happen if milk contacts the  
16       filter. Thus, if the filter becomes wet due to milk and/or water, air can still pass through  
17       the filter because the filter remains permeable to air. An example of such a filter is  
18       Versapor R1200 (part no. 66393) by Pall Corp.

19                  Referring again to Fig. 1, the pump 16 has two halves 104, 106 secured  
20       together by screws or the like 108 to form a chamber 110. The screws 108 also secure a  
21       movable diaphragm 112 in place. The diaphragm 112 divides the chamber 110 into two  
22       halves 110a, 110b.

1           The diaphragm 112 is oscillated in a back and forth manner by a motor 114.  
2       About 41-65 pulsations per minute at the breast (one pulsation being the result of both  
3       a back and forth motion of the diaphragm) are believed to produce suitable results, with  
4       about 52 pulsations per minute producing good results. The motor can be secured to the  
5       housing by bolts 116 or the like.

6           The motor 114 can be a stepper motor, which is one form of a linear  
7       actuator, which has a shaft 118. The shaft 118 moves in and out of the motor 114 in the  
8       axial direction without rotation. The shaft 118 is threaded, and is moved by a rotating  
9       threaded ring 120, which is similar to a nut. Rotation of the ring 120 moves the shaft 118  
10      linearly. In this manner, the shaft 118 can move the diaphragm 112 back and forth  
11      essentially directly, without large, complex linkages.

12           The distal end of the shaft 118 can be guided by an opening 122 in an end  
13      cap 124. The end cap 124 is secured by bolts 126.

14           The pump 16 also has vacuum outlets 128, 130 in the chamber 110, on  
15      opposite sides of the diaphragm 112. The vacuum lines 18, 20 are connected to the  
16      vacuum outlets 128, 130. Check valves such as duck bill valves 136, 138 control the  
17      vacuum and pumping operation, and exhaust valves 140, 142 release the pressure created  
18      in the chamber halves 110a, 110b by the movement of the diaphragm 112. However,  
19      some of the pressure generated by the diaphragm is transmitted through the pressure lines  
20      22, 24 to the collectors 12, 14. The pressure forces the liners 58 against the breasts (see  
21      Fig. 6), which further stimulates release of milk. While the vacuum is fairly continuous,  
22      though, the pressure pulsates, in part because the pressure is quickly bled through vents

1        143 in the pressure lines 22, 24. In fact, when the diaphragm moves away from a pressure  
2        line 22, or 24, air is drawn out and a partial vacuum can be created.

3              Fig. 7 shows the effect of adequately vented pulsation pressure on the  
4        vacuum supplied to the liner. The pump 16 generates a vacuum  $V_{SYS}$ . Without pulsation  
5        pressure, the vacuum is fairly steady at  $V_{SYS}$ . When pressure pulses are applied to the  
6        outside of the liner, though, the vacuum periodically increases to  $V_{PEAK}$ . Those periodic  
7        increases stimulate milk production with less discomfort and a lower  $V_{SYS}$  than is needed  
8        if pressure pulses are not applied.

9              Preferably, a minimum  $V_{SYS}$  of .5" mercury is maintained during use, and  
10       the maximum vacuum  $V_{PEAK}$  does not exceed 5" mercury. The maximum vacuum  $V_{PEAK}$   
11       is preferably 3.0" - 4.1" mercury. However, the maximum differential between  $V_{SYS}$  and  
12        $V_{PEAK}$  is preferably between 1" and 4.5" mercury. The vents 143 are sized to obtain a  
13       desired  $V_{PEAK}$ , and avoid stalling due to overload. If the vents are too small,  $V_{PEAK}$  will  
14       be too high and stalling could occur. If the vents are too large,  $V_{PEAK}$  will be too low.

15              The device is light weight, portable and compact because large motor  
16       linkages are eliminated. Wear is also reduced by simplifying the power train in this  
17       manner. The motor 114 can be any suitable device which creates a fairly self-contained  
18       drive system which is relatively small in size and fairly quiet. In fact, the motor can be  
19       an ordinary motor 114 with a threaded rotating shaft 146, as seen in Fig. 8. In that  
20       embodiment, a fixed ring 148 is attached to the diaphragm. The ring 148 is also threaded,  
21       so when the shaft 146 rotates clockwise and counter-clockwise, the diaphragm 112 moves  
22       back and forth.

1           The motor can be controlled in any suitable manner, such as the control  
2       system 150 shown in Fig. 9. An application specific integrated circuit or the like has a  
3       microprocessor 152 and a ROM 154, programmed to cause a motor driver 156 to set the  
4       desired rate of rotation and the direction of rotation of the motor. The rotation rate, as  
5       well as the timing of the back and forth motion of the diaphragm, can be controlled in this  
6       manner.

7           The diaphragm 112 can be any suitable configuration, such as that shown  
8       in Fig. 1, which features a flat stiff middle section flanked by soft corrugations. Another  
9       design is shown in Figs. 10 and 11, where a diaphragm 158 has a plurality of rings 160  
10      joined by corrugations 162.

11          In use, power is applied to the pump 16, and the expressers 12, 14 are  
12      placed over the breasts. The vacuum  $V_{sys}$  created by the pump 16 secures the expressers  
13      12, 14 on the breasts and helps draw milk from the breasts. The pressure pulsations  
14      massage and compress the breasts to stimulate milk production, and reduce the amount  
15      of vacuum needed to collect the milk. The air pressure lines are vented to obtain strong  
16      pulses without overloading the system. This reduces discomfort to the breasts. The  
17      device can be easily disassembled without tools, cleaned and reassembled.

18          The many advantages of this invention are now apparent. The pulsation  
19      pulses stimulate milk production, without overloading the system due to excessive  
20      pressure build-up in the pressure lines. Cleaning is more convenient because milk does  
21      not enter the vacuum lines. Moreover, the entire collector can be easily disassembled for  
22      cleaning and reassembled without tools. The bosses in the expressers protect the end of

1       the nipple from irritation, which is comfortable. Moreover, the entire pump is small,  
2       lightweight and relatively quiet.

3           While the principles of the invention have been described above in  
4       connection with a specific apparatus and applications, it is to be understood that this  
5       description is made only by way of example and not as a limitation on the scope of the  
6       invention. For example, various aspects of the invention could be used to milk animals,  
7       as well as humans.